DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 23, 2015

Amsel Medical Corporation
% Leo Basta
NorthStar Biomedical Associates
93 Benefit Street
Providence, Rhode Island 02904

Re: K140932
Trade/Device Name: Amsel Occluder Device
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: November 28, 2014
Received: December 1, 2014

Dear Leo Basta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K140932

Device Name: Amsel Occluder Device

Indications for Use:

The Amsel Occluder Device is intended for use in open general surgery procedures on tubular structures or vessels wherever a metal ligating clip is indicated and within the size range of 2.0mm to 7.0mm diameter.

Prescription Use ✓ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Traditional Premarket Notification Submission – 510(k)

510(k) SUMMARY Prepared January 22, 2015

Amsel Occluder Device

510(k) Number K140932

5.1 Company Name

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5.2 Contact Person

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5.3 Trade/Proprietary Name

Amsel Occluder Device

5.4 Classification Name

Clip Implantable

5.5 Product Code/Regulation No.

Product code: FZP, Regulation No. 878.4300.

5.6 Device Classification

Class II

5.7 Panel

General & Plastic Surgery

5.8 Predicate Devices

1. Neurosel Medical Ltd. Twister Superelastic Ligating Clip cleared under K032238, (product code FZP, Regulation No. 878.4300).

2. Ethicon Inc. LigaClip, cleared under K834267 (product code FZP, Regulation No. 878.4300).

5.9 Intended Use

The Amsel Occluder Device is intended for use in open general surgery procedures on tubular structures or vessels wherever a metal ligating clip is indicated and within the size range of 2.0mm to 7.0mm diameter.

5.10 Device Description

The Amsel Occluder Device involves the implantation of a mechanical occlusion device that penetrates into and through the target vessel structure and when compressed and locked, clamps the vessel shut.

The device consists of a metallic clip construct comprised of two compression components and an interlocking implant rod that when compressed together as a unit and locked on either side of a vessel results in occlusion. The delivery device consists of a hand held syringe-like device loaded with the components of the implant construct. The device is for use in general surgical procedures. Once positioned correctly, the occlusion construct is actuated through a series of semi-automatic steps resulting in the two components becoming compressed on either side of the vessel and locked together to occlude the vessel. Once occlusion is achieved, the delivery system, which is mechanically locked to the implant rod, is detached from the implant and the needle is withdrawn leaving the occlusion construct implanted, permanently occluding the vessel.

5.11 Substantial Equivalence

The Amsel Occluder Device is substantially equivalent to the legally marketed predicate devices for the following reasons:

- The Amsel Occluder Device has the same intended use and similar indications for use as the predicate devices,

- All devices use similar technology to deliver a clip to mechanically compress the tissue,
- The Amsel Occluder employs similar or the same materials as its predicates,
- The Amsel Occluder and the predicate devices use a delivery applicator that offers smooth, efficient deployment of the clip/s, and
- All three devices share similar dimensional attributes.

The following table contains a summary of the descriptive and technological characteristics of the Amsel Occluder Device compared to the predicate devices.

	AMSEL OCCLUDER DEVICE	TWISTER SUPERELASTIC LIGATING CLIP	LIGACLIP	SE
510(k) Number	Not yet known	K032238	K834267	
Manufacturer	Amsel Medical Corp.	Neurosel Medical Ltd.	Ethicon Inc.	
Product Code	FZP	FZP	FZP	**Same**
CFR	878.4300	878.4300	878.4300	**Same**
Intended Use & Indications for Use	The Amsel Occluder Device is intended for use in open general surgery procedures on tubular structures or vessels wherever a metal ligating clip is indicated and within the size range of 2.0mm to 7.0mm diameter.	The Twister Superelastic Ligating Clip, Size M is intended for the permanent occlusion or ligation of blood vessels and other tubular body structures, wherever a metal ligating clip is indicated, and within the size range of 2.0 to 3.5mm diameter.	The LIGACLIP MULTIPLE CLIP APPLIER is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.	**Similar. Size range for the Amsel Occluder was demonstrated through animal testing performed using the device.**
Environments of Use	Hospitals and surgery center.	Hospitals and surgery center.	Hospitals and surgery center.	**Same**
Pre Loaded \ Loaded in OR	Pre-loaded	Pre-loaded	Loaded in the OR	**Same as Neurosel**

	AMSEL OCCLUDER DEVICE	TWISTER SUPERELASTIC LIGATING CLIP	LIGACLIP	SE
Clip Size	One size	S,M,L	M,M-L, L	**Clip size range tested in animal and laboratory bench testing demonstrated single clip performs as intended through upper limit labeled vessel size.**
Vessel Size	2.0mm-7.0mm	2.0mm-3.5mm (M)	2.0mm-6.0mm	**Clip size range tested in animal and laboratory bench testing demonstrated single clip performs as intended over labeled vessel size.**
Length of clip	5.5mm	unknown	5.5mm	**Similar. Testing demonstrated that Amsel clip length is sufficient for safe and effective use.**
Secured to vessel or tubular structure	Mechanical, by compressing the clip components (sliding and locking two nitinol elements one against the other on either side of the vessel and locked together with a titanium rod)	Mechanical compression	Mechanical compression	**Same**
Closure method	Penetrating through (transfixing) the vessel using a needle and then deploying locking the vessel externally	External vessel compression	External vessel compression	**Similar. All occlude via external compression of the vessel. Amsel closure technology demonstrated as safe and effective in animal and bench testing.**

	AMSEL OCCLUDER DEVICE	TWISTER SUPERELASTIC LIGATING CLIP	LIGACLIP	SE
Clip Material	Nitinol and titanium	Nitinol	Titanium	**Similar. Amsel uses the same and additional material. All materials tested for biocompatibility and functionality and any differences do not adversely affect safety or effectiveness.**
Single Patient Use, Disposable	Yes	Yes	Yes	**Same**
Sterilization	Sterile for single use EtO	Sterile for single use EtO	Sterile for single use EtO	**Same**
Prescription Use	Yes. The device should be used only by trained surgeon.	Yes. The device should be used only by trained surgeon.	Yes. The device should be used only by trained surgeon.	**Same**

As demonstrated in the completed battery of preclinical tests that were conducted by the company minor technological differences between the Amsel Occluder Device and the predicate devices do not raise new questions of safety and effectiveness. Any minor differences in technological characteristics have been tested and reported on in this notification and demonstrate that such differences do not adversely affect the safety, effectiveness, or intended performance of the device. Therefore, the Amsel Occluder Device is substantially equivalent to the legally marketed predicate devices. Testing in support of the SE determination included laboratory bench testing, biocompatibility testing, shelf life testing and animal testing.

5.12 Performance Characteristics of the Amsel Occluder Device

The Amsel Occluder Device underwent a full battery of bench testing and animal testing to demonstrate its safe and effective performance in occluding vessels. It was concluded that the device is safe and effective for its intended use. Tests were performed in comparison to the predicate device. Specifically, testing included:

- Clip Closure Distance
  - to verify Clip closure distance to ensure it is within the designed specification
- Clip Closure Repeatability and Reliability
  - to verify the repeatable compression and locking of the occluder clip
- Strain Analysis
  - the purpose was to analyze the maximal strain of the clips during occlusion
- Corrosion Test
  - Verification that the device does not develop corrosion post implantation. Testing was performed per ASTM 2129-08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices and ASTM F3044-14 Test Method for Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants
- Performance Evaluation
  - to verify the performance of the Amsel Occluder device in a simulated model
- Device to Implant Detachment Force
  - to verify that the force required to detach the clip from the delivery system is sufficiently robust to prevent inadvertent detachment of the delivery system from the clip
- Holding Pressure Evaluation
  - verification of occlusion performance by pressurizing occluded structure through pressures over 700mmHg
- Release Mechanism Function Testing
  - to verify proper detachment of the delivery system from the implant during operation

- Deployment Force Testing
  - The force required to deploy the Amsel Occluder Device was tested in comparison to a predicate. Results were that the Amsel device took less force than the predicate to deploy the device
- Biocompatibility Testing
  - to verify that all body contact materials are biocompatible for the contact and duration of contact
- Animal study including holding pressure and histology
  - preclinical *in-vivo* use of the Amsel device compared to a predicate device to evaluate the safety and effectiveness of the Amsel device in terms of introduction, deployment, usability, and occlusion performance in arteries and veins 2.0mm to 7.0mm
- MR Imaging Testing
  - to support the MR conditional claim in the device's labeling.

All testing performed demonstrated that the Amsel Occluder is a safe and effective device for vessel and tubular structure occlusion and is considered substantially equivalent to its predicate devices.

5.13 Conclusion

Amsel Medical believes that, based on the descriptive information and testing provided in this submission, the Amsel Occluder Device is substantially equivalent to its predicate devices.